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Long-Term Results After Directional Atherectomy of Femoro-Popliteal Lesions

Thomas Zeller, MD,* Aljoscha Rastan, MD,* Sebastian Sixt, MD,* Uwe Schwarzwälder, MD,* Thomas Schwarz, MD,* Ulrich Frank, MD,* Karlheinz Bürgelin, MD,* Christian Müller, MD,† Uwe Rothenpieler, MD,* Peter-Christian Flügel, MD,* Gunnar Tepe, MD,‡ Franz-Josef Neumann, MD, FACC*

Bad Krozingen and Tübingen, Germany; and Basel, Switzerland

OBJECTIVES Our objective in this research was the evaluation of the long-term results after directional atherectomy using the Silverhawk device (FoxHollow Technologies, Redwood City, California) of femoro-popliteal lesions.

BACKGROUND Considering reports on stent fractures in femoro-popliteal arteries, atherectomy may be a valuable alternative to stenting.

METHODS Eighty-four patients with 100 legs and 131 lesions with peripheral occlusive disease Rutherford categories 2 to 5 were included in a prospective registry. Forty-five lesions were de novo lesions (group 1; 34%), 43 lesions native vessel restenoses (group 2; 33%), and 43 lesions in-stent restenoses (group 3; 33%). Additional low pressure balloon angioplasty was used in 78 of 131 lesions (59%) and stenting in 8 lesions (6%).

RESULTS Technical success rate was 86% for atherectomy only and 100% after additional therapy. Mean lesion length was 43 ± 54 mm, 105 ± 122 mm, and 131 ± 111 mm for group 1, group 2, and group 3, respectively ($p < 0.001$). Primary patency, defined as freedom of a >50% restenosis detected by duplex, was 84%, 54%, and 54% at 12 months ($p = 0.002$) and 73%, 42%, and 49%, at 18 months ($p = 0.008$); secondary patency rates were 100%, 93%, and 91% at 12 months (p = NS) and 89%, 67%, and 79% at 18 months ($p = 0.001$), respectively; and target lesion revascularization rate was 16%, 44%, and 47% at 12 months and 22%, 56%, and 49% at 18 months ($p = 0.003$ each) for group 1, group 2, and group 3, respectively. The only independent predictor for restenosis was treatment of restenotic lesions. Ankle-brachial index was significantly improved after 12 months and 18 months in all groups.

CONCLUSIONS Long-term technical and clinical results after directional atherectomy of femoro-popliteal lesions are in favor of de novo lesions compared with restenotic lesions. (J Am Coll Cardiol 2006;48:1573–8) © 2006 by the American College of Cardiology Foundation

Balloon angioplasty of femoro-popliteal lesions is limited by a low primary patency rate of 30% to 61% after 3 years depending on lesion length and clinical stage (1–5). Stenting initially resulted in disappointing long-term results with 1-year primary patency rates of 22% for the balloon-expandable Palmaz stent (Cordis Corp., Haan, Germany) (6) and of 30% for the self-expanding Wallstent (Boston Scientific, Natick, Massachusetts) (7); the primary patency had been substantially improved to 61% for the SMART nitinol stent (Cordis Corp.) (7,8). However, the patency rate of nitinol stents seems to be dependent on the type of stent implanted (8,9). Another not yet completely understood issue is the impact of stent fractures on long-term patency and formation of pseudoaneurysms (8,9). Percutaneous removal of obstructive material through directional atherectomy represents a theoretical approach for reducing restenosis rate. Whereas older single-center studies with the Simpson Atherocath report high primary success rates and acceptable long-term results for the treatment of femoro-popliteal lesions (10–14), 2 randomized trials found similar results as for conventional balloon angioplasty (15,16). This, along with the demanding technique, prevented atherectomy to become established as a routine technique. The introduction of the easy-to-use Silverhawk device (FoxHollow Technologies, Redwood City, California) has re-established the use of directional atherectomy with promising acute technical and clinical success rates and mid-term patency rates for the treatment of femoro-popliteal lesions (17,18). Nevertheless, long-term data are still lacking.

We here report the prospective single-center long-term results after treatment of femoro-popliteal lesions with the Silverhawk atherectomy catheter (FoxHollow Technologies).

METHODS

In this prospective single-center study between June 2002 and May 2004, 84 patients with femoro-popliteal lesions with chronic peripheral occlusive disease (POD) Rutherford categories 2 to 5 were treated with directional atherectomy.

The following inclusion criteria were prospectively defined:

1. Stable chronic POD (e.g., no change of the Rutherford category during the last 3 months before study inclusion) with an ankle-brachial index at rest <0.85.
2. Reference vessel diameter 3 to 7 mm.

From the *Department of Angiology, Herz-Zentrum Bad Krozingen, Bad Krozingen, Germany; †Department of Internal Medicine, University Hospital Basel, Basel, Switzerland; and the ‡Department of Diagnostic and Interventional Radiology, University Hospital Tübingen, Tübingen, Germany.

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Abbreviations and Acronyms

ASA = acetylsalicylic acid
MLD = minimal lumen diameter
POD = peripheral occlusive disease
SFA = superficial femoral artery
TALON = Treating peripherALs with silverhawk: Outcomes collectioN registry

3. Degree of stenosis >70%.
4. No complete intraluminal calcification in the lesion detected by pre-interventional ultrasound.

We excluded patients with acute occlusions and/or with angiographically visible thrombus.

The study was approved by the local ethics committee, and all patients gave written informed consent to participate.

A 7-F sheath (Avanti, Cordis; or Balkin, Cook, Bjaeverskov, Denmark) that is compatible with a monorail-guided atherectomy catheter (Silverhawk P4010 or P4011 debulking catheter, FoxHollow) was used. The target vessels included superficial femoral artery (SFA; n = 86), popliteal artery (n = 30), and lesions including the distal SFA and proximal popliteal artery (n = 15), which were counted as 2 lesions (SFA and popliteal artery). Forty-five lesions were de novo lesions (group 1; 34%), 43 lesions native vessel restenoses (group 2; 33%), and 43 lesions in-stent restenoses (group 3; 33%). One, 2, 3, or 4 lesions were treated in 74, 23, 2, and 1 limbs, respectively. Thirty-six patients were diabetic patients (43%) (Table 1). Angiographic measurements of the vessel and lesion diameters were performed using the automated contour detection program of the angiography unit (Angiostar and Multistar, Siemens, Erlangen, Germany). Based on these measurements, the degree of the diameter stenosis was calculated.

The pre- and post-interventional (before discharge, after 6, 12, and 18 months) diagnostics included, in addition to a clinical examination, the Doppler occlusive pressure measurement with a calculation of the ankle-brachial index, color duplex sonography, and the determination of routine laboratory parameters. Restenosis definition was based on duplex ultrasound with a >50% restenosis defined as a proximal systolic peak flow velocity ratio >2.4 (17). Clinical improvement was expressed as difference in Rutherford classes after 18 months.

All lesions were treated primarily with the Silverhawk catheter (FoxHollow Technologies). The number of lesion passes was left to the discretion of the interventionist. The catheter function of the 0.014-inch wire-guided device had already previously been described (18,19). The 7-F sheath-compatible device was designed for the treatment of vessel diameters of 3 to 7 mm. The use of an additional low pressure balloon was left to the discretion of the interventionist. However, the balloon pressure should not exceed 3 atm. Stenting was discouraged and only allowed with flow-limiting dissection (bail out indication) or a residual stenosis after atherectomy and low-pressure balloon angioplasty.

Medical therapy. Post-interventional therapy consisted of acetylsalicylic acid (ASA), 100 mg/day for life, and clopidogrel, 75 mg/day, for 4 weeks. The antiplatelet therapy was started at the latest the day before the intervention with a loading dose of clopidogrel of 600 mg and 500 mg of ASA. Peri-interventional administration of 2,500 to 5,000 international units of heparin was given intra-arterially after sheath placement. The dose of heparin was depending on the length of the intervention; after sheath placement, a bolus of 2,500 international units was given and repetitively administered if the intervention extended 1 h. None of the interventions in this study lasted longer than 2 h, so that the maximum heparin dose was 5,000 international units. Activated clotting time (ACT) measurement was not done routinely.

Statistics and definitions. For continuous variables, values are given as the average value ± SD, and for discrete variables, values are the number of patients or lesions and

Table 1. Baseline Characteristics Stratified to the Subcohorts

	Group 1, De Novo Lesions	Group 2, Restenotic Lesions	Group 3, In-Stent Restenoses	p Value
Lesions (n)	45	43	43	0.60
Male gender (%)	80	50	58	0.044
Age (yrs)	63 ± 9	65 ± 11	67 ± 10	0.16
Diabetes mellitus (%)	47	37	42	0.73
Smoker (%)	77	80	71	0.68
Hyperlipidemia (%)	87	97	97	0.14
Hypertension (%)	80	90	92	0.29
SFA (n)*	39 (87%)	32 (64%)*	32 (63%)*	0.27
Popliteal artery (n)*	6 (13%)	18 (36%)*	19 (37%)*	0.003
Lesion length (mm)	43 ± 54	105 ± 122	131 ± 111	<0.001
Reference diameter (mm)	5.12 ± 1.03	4.90 ± 0.7	4.94 ± 0.66	0.096
MLD (mm)	0.80 ± 0.60	0.67 ± 0.60	0.74 ± 0.74	0.78
Diameter stenosis (%)	85 ± 11	87 ± 11	88 ± 9	0.50
ABI at baseline	0.60 ± 0.19	0.52 ± 0.22	0.58 ± 0.38	0.60

*Including lesions lasting from the distal SFA to the popliteal artery counted as SFA *and* popliteal artery.
ABI = ankle brachial index; MLD = minimal lumen diameter; SFA = superficial femoral artery.

percent. Comparisons were made using analysis of variance, chi-square test, and Fisher exact test as appropriate. Analyses were by lesion except the Kaplan-Meier event-free survival curves for survival without target vessel revascularization. All hypothesis testing was 2-tailed, and a value of $p < 0.05$ was considered significant. Kaplan-Meier analysis was applied to calculate cumulative long-term survival. Cox regression analysis was used to identify independent predictors of restenosis. Variables associated with restenosis in univariable analysis with a value of $p < 0.05$ were entered into the multivariable model.

Technical success after atherectomy was defined as ≤50% residual stenosis; procedural success was defined as ≤30% residual stenosis. Primary patency is defined as freedom of restenosis >50% calculated by duplex ultrasound without any reintervention at the level of the target lesion at the time of follow-up visit. Secondary patency is defined as freedom of restenosis >50% at the time of follow-up visit after reintervention in case of restenosis or reocclusion of the target lesion before the follow-up visit. The indication for target lesion revascularization rate was exclusively driven by recurrent symptoms. Change of ankle brachial index or a rise in peak velocity ratio detected by duplex ultrasound only without concomitant life-style–limiting symptoms or recurrent critical limb ischemia did not lead to reintervention.

RESULTS

A total of 84 patients (64% male patients, mean age 66 ± 12 years, range 40 to 88 years) with 100 lower limbs and 131 femoro-popliteal lesions were entered into this study. Patients' baseline characteristics are shown in Table 1. Total occlusions were treated in 8.5%. The average lesion length was 90 ± 106 mm (range 10 to 400 mm) with significantly longer lesions in groups 2 and 3 (Table 2). Mean lesion length was 43 ± 54 mm, 105 ± 122 mm, and 131 ± 111 mm for group 1, group 2, and group 3, respectively ($p < 0.001$; Table 2). Technical and procedural success was achieved in all interventions according to the prospectively defined criteria. After atherectomy alone, in 126 of 131 (96%) lesions, residual stenosis was ≤50% (technical success), and in 100 of 131 (76%) residual stenosis was ≤30% (procedural success). Additional low pressure balloon angioplasty using a balloon catheter sized adequately to the reference vessel diameter with maximum 4 atms of pressure applied by an in-deflator was performed in 78 of 131 lesions (59%) and stenting in 8 lesions (6%). The reason for low pressure after dilatation was either to achieve procedural success (24%) or the angiographic appearance of haziness without a focal residual stenosis with the goal of smoothing the vessel surface with balloon angioplasty. Stent implantation was indicated in 1 case of a type C dissection after post-dilatation; in another case, an already pre-interventionally detected stent fracture of a previously implanted stent led to a stent-in-stent placement. In the remaining cases, residual stenoses of about 50% after additional balloon angioplasty due to heavily or eccentric calcification prompted stent implantation.

The mean percent diameter stenosis for the entire study cohort was 87 ± 10% with an average minimal lumen diameter (MLD) of 0.73 ± 0.65 mm (mean angiographic proximal reference vessel diameter: 5.0 ± 0.69 mm) without significant difference between the 3 subgroups (Table 2). The average percent diameter stenosis after atherectomy was reduced from 87 ± 10% (range 70% to 100%) to 27 ± 17% (range 0% to 100%), and the MLD increased from 0.88 ± 0.7 mm to 3.7 ± 0.9 mm (range 0 to 5.5). After additional balloon dilatation or stent implantation, the percent diameter stenosis further decreased to 12 ± 10% (0% to 30%), and the final MLD was 4.5 ± 0.8 mm (range 3.6 to 5.5 mm). The procedural outcome data stratified for the 3 subcohorts are plotted in Table 2.

Twelve- and 18-month follow-up was complete for all surviving patients (n = 81) (Fig. 1). Three patients died during follow-up, 1 because of prostate cancer, 2 patients due to myocardial infarction.

Primary patency was 84%, 54%, and 54% at 12 months ($p = 0.002$) and 73%, 42%, and 49% at 18 months ($p = 0.008$) for group 1, group 2, and group 3, respectively. Secondary patency rates were 100%, 93%, and 91% at 12 months (p = NS) and 91%, 65%, and 76% at 18 months ($p = 0.001$), respectively. Target lesion revascularization rate was 16%, 44%, and 47% at 12 months ($p = 0.003$) and 22%, 54%, and 49% at 18 months ($p = 0.003$) for group 1, group 2, and group 3, respectively (Table 3). Figure 2 shows the Kaplan-Meier event-free survival curves for survival without target vessel revascularization.

Multivariable regression analysis identified the treatment of restenotic lesions as the only independent predictor for restenosis (Table 3).

Table 2. Acute Results, Subgroup Analysis

	Group 1, De Novo Lesions	Group 2, Restenotic Lesions	Group 3, In-Stent Restenoses	p Value
MLD post-atherectomy (mm)	3.86 ± 0.95	3.76 ± 0.74	3.59 ± 1.1	0.40
DS post-atherectomy (%)	26 ± 17	25 ± 15	29 ± 19	0.51
MLD final (mm)	4.58 ± 0.68	4.58 ± 0.69	4.38 ± 0.89	0.53
DS final (%)	14 ± 9	9 ± 8	13 ± 13	0.06
Balloon angioplasty	25/45 (56%)	28/43 (65%)	28/43 (65%)	0.6
Stenting (%)	1/45 (2%)	3/43 (7%)	4/43 (9%)	0.4
ABI before discharge	0.90 ± 0.17	0.78 ± 0.20	0.86 ± 0.35	0.18

ABI = ankle brachial index; DS = diameter stenosis; MLD = minimal lumen diameter.

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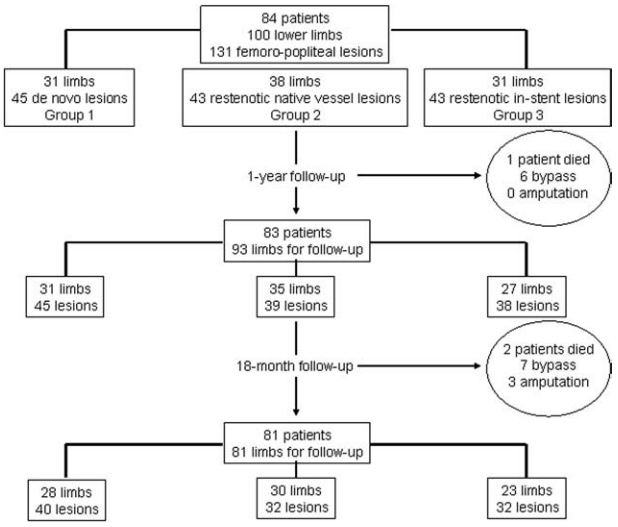

Figure 1. Study profile.

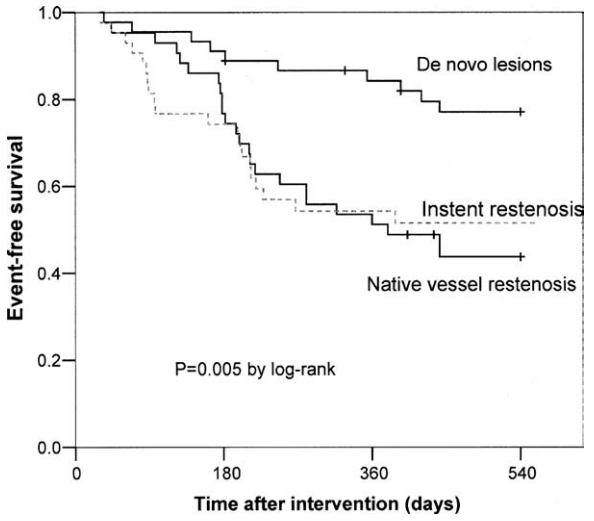

Figure 2. Kaplan-Meier event-free survival curves for survival without target vessel revascularization.

Compared with baseline, the ankle-brachial index was significantly improved after 12 months and 18 months in all groups (group 1: 0.60 ± 0.19 vs. 0.80 ± 0.20 vs. 0.77 ± 0.27 [$p < 0.001$]; group 2: 0.52 ± 0.22 vs. 0.70 ± 0.35 vs. 0.74 ± 0.23 [$p < 0.001$]; group 3: 0.58 ± 0.38 vs. 0.80 ± 0.29 vs. 0.79 ± 0.35 [$p < 0.001$]) (Table 4).

Changes in at least 2 Rutherford categories after 18 months were significantly more frequently found for patients in group 1 compared with groups 2 and 3, respectively, despite the fact that there was no significant difference in ankle-brachial index at 18 months (Table 4). No patient of group 1 underwent major amputation, whereas 1 patient of group 2 and 2 patients of group 3 underwent below-the-knee amputation during follow-up (Table 3). There was no difference in bypass graft frequency among the 3 groups ($p = 0.722$) (Table 4).

Complications. During the first 8 interventions, 5 peripheral emboli of atherectomized wall components were observed. They could be completely removed by aspiration with a 5-F or 6-F aspiration catheter in a single aspiration maneuver. The embolized material came out each time through the small vent hole near the end of the catheter tip. After the catheter tip was emptied after no more than 4 passages through stenosed areas and the reservoir was technically modified, there were no further emboli. A type C dissection after additional balloon dilatation had to be treated with a stent (SMART control, Cordis). There were 10 occasions where the blade became temporarily bound while in the forward position in the catheter tip (reservoir). This occurred only when the vessel had a bend or turn; it happened 6 times during cross-over application of the device. The blade could always be freed by turning the locking rotator. No vessel wall perforation was observed.

DISCUSSION

We report on the long-term results of a prospective cohort of patients with femoro-popliteal lesions treated with the Silverhawk directional percutaneous atherectomy catheter system (FoxHollow Technologies). Initial acute and mid-term results reported promising results comparable to the outcome of nitinol stents in the same vessel area (19).

Table 3. Univariable and Multivariable Analysis of Predictors of Restenosis After Directional Atherectomy

	Univariable Analysis				Multivariable Analysis			
	HR	Lower 95% CI	Upper 95% CI	p Value	HR	Lower 95% CI	Upper 95% CI	p Value
Native vessel restenosis	3.904	1.575	9.680	0.003	2.34	1.08	5.06	0.031
In-stent restenosis	3.238	1.309	8.008	0.011	2.59	1.19	5.65	0.017
Mean reference vessel diameter	0.392	0.216	0.711	0.002	0.70	0.45	1.10	0.123
Mean lesion length	1.005	1.002	1.009	0.004	1.001	0.998	1.003	0.621
Diameter stenosis at baseline	1.064	1.023	1.106	0.002	0.95	0.87	1.04	0.306
MLD at baseline	0.270	0.128	0.570	0.001	0.21	0.04	1.19	0.078
Age	0.983	0.943	1.024	0.410				
ABI at baseline	0.392	0.088	1.750	0.220				
Hypercholesterolemia	2.873	0.573	14.394	0.199				
Smoking	1.169	0.521	2.626	0.705				
Diabetes	0.714	0.355	1.436	0.345				
Hypertension	0.646	0.233	1.797	0.403				

ABI = ankle brachial index; CI = confidence interval; HR = hazard ratio; MLD = minimal lumen diameter.

Table 4. Long-Term Results Subcohort Analysis Per Lesion

	Group 1, De Novo Lesions	Group 2, Restenotic Lesions	Group 3, In-Stent Restenoses	p Value
Primary patency 12 months (%)	84	54	54	0.002
Secondary patency 12 months (%)	100	93	91	0.1
TLR 12 months (%)	16	44	47	0.003
ABI 12 months	0.80 ± 0.20	0.70 ± 0.35	0.80 ± 0.29	0.36
Primary patency 18 months (%)	73	42	49	0.008
Secondary patency 18 months (%)	91	65	76	0.001
TLR 18 months (%)	22	56	49	0.003
ABI 18 months	0.77 ± 0.27	0.74 ± 0.23	0.79 ± 0.35	0.87
Improvement of >2 Rutherford categories at time of latest follow-up	84%	53%	62%	0.027
Bypass surgery	3/31 limbs (9.7%)	6/38 limbs (15.8%)	4/31 limbs (12.9%)	0.722
Amputation (n)	0	1	2	

ABI = ankle brachial index; TLR = target lesion revascularization.

Compared with the Simpson Atherocath that was not established for treatment of femoro-popliteal lesions in the early 1990s because of its complex operation and missing superiority over balloon angioplasty (10–16), the Silverhawk system (FoxHollow Technologies) is simple to operate and therefore could contribute to a rebirth of directional atherectomy.

Atherectomy alone, in the majority of cases (97%), led to technical success defined as ≤50% residual stenosis; additional balloon dilatation in most cases served to visually improve the appearance with clarified stenosis contours; in 24% balloon angioplasty was necessary to reach the prospectively defined procedural success (≤30%). Thus, the initial use of the system tested here is more successful than that of the old Simpson Atherocath, reporting primary success rates of 82% to 100% (12,20). Additional stent implantation was indicated only in a minority of lesions.

The only 2 randomized comparative studies for the treatment of femoro-popliteal lesions between atherectomy with the Simpson Atherocath and balloon dilatation were not able to demonstrate any advantage for atherectomy (15,16), however, individual single-center studies showed positive long-term results (10–14,20–24). In our study cohort, long-term results are encouraging considering the fact of including mostly challenging lesions into the study. The best outcome results were found for de novo lesions with 12- and 18-month primary patency rates of 84% and 73%, respectively. However, also for in-stent restenotic lesions, primary 12-month patency rate is higher than reported for a rotational thrombectomy device (Straub-Rotarex, Straub Medical, Wangs, Switzerland, 54% vs. 31% [25]), which also atherectomizes neointima if the device gets in direct contact with the vessel wall.

Despite a significantly shorter mean length of the de novo lesions, multivariable analysis identified restenotic lesion, regardless of whether native vessel or in-stent restenosis was the only independent predictor of restenosis.

The results presented here are not comparable with the multicenter TALON (Treating peripherALs with silverhawk: Outcomes collectioN) Registry. In this registry, a mixed cohort of lower extremity lesions including iliac arteries, femoro-popliteal arteries, and below-the-knee vessels were analyzed regarding freedom of target vessel revascularization rate reporting 90% and 80% at 6 months and 12 months, respectively. However, the results of the TALON Registry (26) are not based on any objective imaging techniques like duplex ultrasound, intra-arterial or magnetic resonance, or computed tomography angiography to determine the real restenosis rate.

The major finding of this study is that atherectomy of de novo femoro-popliteal lesions with the Silverhawk catheter (FoxHollow Technologies) achieves comparable 1-year (16%) and 18-month (27%) binary restenosis rates compared with stenting using current bare and drug-coated nitinol stents. The SIROCCO (Sirolimus-Eluting versus Bare Nitinol Stent for Obstructive Superficial Femoral Artery Disease) Trial (27) currently representing the most favorable outcome data for nitinol stents in the SFA comparing the result of the treatment of de novo SFA lesions with bare SMART nitinol stents (Cordis Corp.) and sirolimus-coated SMART stents, respectively, resulted in a binary restenosis rate at 18 months of 18% and 21%, respectively. The data regarding the good 1-year performance of the SMART nitinol stent are confirmed by the registry data of Scheinert et al. (9) (and unpublished data presented at Transcatheter Cardiovascular Therapeutics, 2004) who found a 1-year primary patency of 82% for this particular stent type. However, 2 other prospectively examined stent types had less favorable 1-year primary patency rates of 44% (7-F SelfEx, Abbott-Jomed, Redwood City, California) and 27% (Luminexx, Bard, Murray Hill, New Jersey), respectively, which are considerably lower compared with those we have found for directional atherectomy.

Considering the still unresolved issue of stent fractures after SFA and popliteal artery stenting (8,9,28), any technology that improves the acute technical result of angioplasty avoiding stenting should be beneficial. Atherectomy potentially reduces barotraumas—vessel wall injury from irregular tears, splits, and stretches—caused by balloon angioplasty often demanding stent placement.

Limitations of this study are the mixed study population regarding inclusion of de novo lesions, restenotic nonstented and stented vessel segments, and the inclusion of SFA and popliteal artery lesions. Furthermore, this is not a randomized study including a reference group undergoing balloon angioplasty. Further studies have to examine the best use of the Silverhawk (FoxHollow Technologies) atherectomy device regarding long-term patency: plain atherectomy to avoid barotrauma induced by additional balloon angioplasty or atherectomy combined with balloon angioplasty to achieve the best acute MLD. Furthermore, it would be of interest if an intravascular-ultrasound-guided optimized atherectomy technique would achieve better long-term patency results than reported in the present study.

Reprint requests and correspondence: Dr. Thomas Zeller, Department of Angiology, Herz-Zentrum Bad Krozingen, Südring 15, D-79189 Bad Krozingen, Germany. E-mail: thomas.zeller@herzzentrum.de.

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